K123007

510(k) Summary

JUN 19 2013

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 05/27/2013

1. Submitter:

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2. Submission Correspondent:

Priscilla Chung
LK Consulting Group
1515 E Katella Ave Unit 2115,
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3. Device:

Proprietary Name:	Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System Veri-Q plus MGD-1001 Blood Glucose Monitoring System
Common Name:	Blood Glucose Test System
Classification Name:	System, Test, Blood Glucose, Over The Counter Glucose Oxidase Single(specified) analyte controls
Classification:	Class II, 21 CFR 862.1345
Classification Product Code:	NBW
Subsequent Product Codes	CGA, JJX

4. Predicate Device:

CareSens N(K083468) by i-SENS, Inc.

5. Description:

The proposed Veri-Q self-testing / plus MGD-1001 Blood Glucose Monitoring System consists of a meter, test strips, control solutions (3 levels), a lancing device and sterile lancets. The blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement. The Veri-Q self-testing / plus MGD-1001 meter is a no-code meter, so the responsibility of coding has been removed from the user. Each individual test strip contains technology that allows it to automatically calibrate and code the meter once it is inserted.

6. Indications for use:

6.1 Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System

The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).
The Veri-Q self-testing MGS-01 test strips are for use with the Veri-Q self-testing MGD-1001 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm.
The Veri-Q self-testing Glucose Control Solutions are for use with the Veri-Q self-testing MGD-1001 meter and the Veri-Q self-testing MGS-01 test strips to check that the meter and test strips are working together properly and providing accurate results.

6.2 Veri-Q plus MGD-1001 Blood Glucose Monitoring System

The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose (sugar) in fresh capillary whole blood drawn from fingertips, palm, or forearm. The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use). The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling lancing devices. The Veri-Q plus MGD-1001 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).
The Veri-Q plus MGS-01 test strips are for use with the Veri-Q plus MGD-1001 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm.

The Veri-Q plus Glucose Control Solutions are for use with the Veri-Q plus MGD-1001 meter and the Veri-Q plus MGS-01 test strips to check that the meter and test strips are working together properly and providing accurate results.

7. Technological Characteristics:

The Veri-Q self-testing / plus MGD-1001 Blood Glucose Monitoring System has the same fundamental scientific technology as the predicate device. The indications for use, technology, design of glucose meter, and strips are almost the same. The major difference is that for the Veri-Q meter, non coding is required on user side but the predicate device employs auto-coding method. There are also minor difference such as shelf life and memory capacity.

8. Performance Data:

The testing for the Veri-Q self-testing / plus MGD-1001 Blood Glucose Monitoring System was performed in accordance with ISO 15197:2003. Clinical evaluation included method comparison, user performance and alternative-site blood glucose measurement. Non-clinical performance evaluations were conducted to establish the performance, functionality and reliability characteristics of the Veri-Q self-testing / plus MGD-1001 Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

9. Conclusions:

MiCoBioMed Co., Ltd. concludes that the Veri-Q self-testing / plus MGD-1001 Blood Glucose Monitoring System is safe and effective also, substantially equivalent to the predicate device.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2013

MiCoBioMed Co., Ltd.
C/O Priscilla Chung
C/O LK Consulting Group
1515 E. Katella Ave, Unit 2115
ANAHEIM CA 92805

Re: K123007
Trade/Device Name: Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System
Veri-Q plus MGD-1001 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: May 28, 2013
Received: May 30, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K 123007

Device Name: Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System

Indication for use:

The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Veri-Q self-testing MGS-01 test strips are for use with the Veri-Q self-testing MGD-1001 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm.

The Veri-Q self-testing Glucose Control Solutions are for use with the Veri-Q self-testing MGD-1001 meter and the Veri-Q self-testing MGS-01 test strips to check that the meter and test strips are working together properly and providing accurate results.

Prescription Use_____ AND/OR Over-The-Counter Use ✓
(Part 21CFR801 Subpart D) (Part 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro and Radiological Health
Evaluation and Safety

510(k) k123007

Indications for Use

510(k) Number K 123007

Device Name: Veri-Q plus MGD-1001 Blood Glucose Monitoring System

Indication for use:

The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose (sugar) in fresh capillary whole blood drawn from fingertips, palm, or forearm. The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use). The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling lancing devices. The Veri-Q plus MGD-1001 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Veri-Q plus MGS-01 test strips are for use with the Veri-Q plus MGD-1001 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm. The Veri-Q plus Glucose Control Solutions are for use with the Veri-Q plus MGD-1001 meter and the Veri-Q plus MGS-01 test strips to check that the meter and test strips are working together properly and providing accurate results.

Prescription Use ✓ AND/OR Over-The-Counter Use ✓

(Part 21CFR801 Subpart D) (Part 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro and Radiological Health (OIR)

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Office of In Vitro and Radiological Health
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